

REMARKS

Applicants were asked to submit formal drawings to address objections to the drawings on form PTO-948 mailed with Paper No. (no number given, mailed January 30, 2002). Applicants are herewith submitting formal, corrected drawings (1A-1C, 2, 3A-3C, 4-9). No changes to the drawings were made other than to correct informalities noted by the Draftsperson on form PTO-948. Applicants request review of the new drawings to confirm that the objections have been corrected and acceptance of the drawings as formal drawings.

Applicants have amended the specification to update references to Figures 1 and 3 in the specification to correspond with the formal drawings submitted herewith. A marked-up version of the paragraphs with the respective amendments is enclosed herewith. No new matter has been added.

**REJECTION OF CLAIMS 1 THROUGH 27 UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. According to the Examiner, claims 1-27 are readable on a genus of a non-human transgenic animal, wherein the genus of the transgenic animal is not claimed in a specific biochemical or molecular structure.

The Applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution of the present application, Applicants have canceled claims 2, 4, 6, 7, 9, 11, 12, 14, 16-20, 22, and 25. Applicants also have amended claims 1, 3, 5, 8, 10, 13, 15, 21, 23, and 24 to refer a transgenic mouse. Applicants' new claims 28-30 also refer to a transgenic mouse. This transgenic mouse term replaces the terms "non-human transgenic animal" or "mammal" in the claims as previously written. The Examiner states, on page 4 of the Office Action, that the specification provides sufficient guidance of a species of characteristics from a transgenic mouse. The Examiner's rejection with regard to the amended claims therefore should be withdrawn.

Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution of the present application, Applicants have canceled claims 16- 20 and have amended claim 15 to refer to a thrombotic response rather than a biological response. This limitation imparts to claim 15

the species of specific biological response originally referred to in claim 18. In view of this amendment, Applicants respectfully request that this rejection be withdrawn.

Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution of the present application, Applicants have canceled claim 22 and have amended claim 21 and have added new claims 28-30 to refer to specific characteristics described in the specification as characteristics related to glycoprotein V function, e.g. on page 6 lines 19-24 and page 25 lines 5-21. In view of this amendment and the new claims, Applicants respectfully request that this rejection be withdrawn.

#### **REJECTION OF CLAIMS 1 THROUGH 27 UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 1-27 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the full scope of the invention. The Examiner argues that the specification does not enable one skilled in the art to produce a non-human animal comprising a modified GP V gene, but does enable a transgenic mouse.

The Applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution of the present application, Applicants have canceled claims 2, 4, 6, 7, 9, 11, 12, 14, 16-20, 22, and 25 and have amended claims 1, 3, 5, 8, 10, 13, 15, 21, 23, and 24 to refer to a transgenic mouse rather than a nonhuman transgenic animal or mammal. Thus, as the Examiner states that the specification is enabling for the production of transgenic mice, this rejection should be withdrawn.

The Examiner's argument that the specification fails to enable the production of or describe a phenotype of a mouse comprising a modified GP V gene other than with a homozygous disruption of GP V is respectfully traversed. The method to make other than homozygous mice, e.g. the heterozygous mouse, is enabled on page 6, lines 13-16 and in Methods pages 14-15 and as acknowledged by the Examiner on page 10 of the Office Action. The methods and results related to the study of the effects of a transgenic mouse with a modification other than a homozygous disruption of GP V gene, e.g. the heterozygous transgenic mouse with a modified GP V gene, are described in Examples 3-6. The heterozygous transgenic mice had results intermediate between the wild type and the homozygous transgenic mice as described in the Examples. While some of these intermediate differences in results with the heterozygous animals between wild type and homozygous transgenic mice were statistically insignificant, e.g. average bleeding time as noted by the examiner, some differences, e.g. the results for

fibrinogen binding at low concentrations of thrombin, platelet aggregation response and percent of mice with bleeding times greater than 500 seconds, were statistically significant. These differences enable one skilled in the art to test the heterozygous phenotype, in contrast to the Examiner's assertions on page 14. Thus Applicants respectfully request that this rejection be withdrawn.

Claims 15-22 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the full scope of the invention. Applicants have canceled claims 16-20 and 22, have amended claims 15 and 21 and have added new claims 28-30 to recite a specific biological response and specific characteristics displayed by a transgenic mouse which does not express a functional GP V protein or expresses a GP V protein which demonstrates a reduced functionality as compared with the native or wild-type GP V protein. These limitations are enabled in the specification and would not require undue experimentation for one skilled in the art to practice the claimed invention in the mouse species. Thus, Applicants respectfully request that this rejection be withdrawn.

#### CONCLUSION

The foregoing amendments and remarks are being made to place the Application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims.

This paper is being filed timely within the three month period for response. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

31 March 2003

Respectfully submitted,

MILLENNIUM PHARMACEUTICALS, INC.

By Tracy M. Sioussat  
Tracy M. Sioussat  
Registration No. 50,609  
75 Sidney Street  
Cambridge, MA 02139  
Telephone - 617-374-7679  
Facsimile - 617-551-8820